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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,356	08/27/2001	Gust H. Bardy	032580.0023.UTL	5199

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GOTTLIEB, RACKMAN & REISMAN, P.C.
270 MADISON AVENUE
NEW YORK, NY 10016-0601

EXAMINER

JASTRZAB, JEFFREY R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,356

Applicant(s)

BARDY ET AL.

Examiner

Jeffrey R. Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-214 is/are pending in the application.
- 4a) Of the above claim(s) 185-214 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-184 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species 27 in Paper No. 8 is acknowledged.

Claims 185-214 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the detailed description of the elected embodiment fails to reference "channel guides".

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the channel guides being on the first and second side of the electrode, e.g. Claim 3 must be shown in the elected embodiment's figures or the feature(s) canceled from the claim(s). No new matter should be entered.

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A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 32, 35-43, 45-47, 78, 81-89, 91-93, 124, 127-135, 137-138 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Osypka, US-5003990. Note Figure 3 for example wherein two channel guides are used for aiding implantation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman et al. or in the alternative in view of Parks, US-5050600. Heilman et al. disclose the invention substantially as claimed, however only one channel guide (pocket)(50) is shown. The addition of a second such channel guide adds no significant patentable difference absent any teaching of unexpected result. In the instant case, the additional guide merely adds an additional degree of guidance for implantation. Therefore, adding an additional channel guide to the Heilman et al. device would have amounted to a mere duplication of parts and thus an obvious design expedient to those skilled in the art at the time of the invention. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Alternatively, Park teaches a pacer lead with a fin (36) for gripping during electrode insertion it would have been obvious to have incorporated the fin arrangement of Parks into the Heilman et al. device in order to add a further degree of maneuverability to the electrode insertion and implantation process.

As to Claim 3 and the like, the location of the additional guide would have been a matter of choice in design. As to Claim 7, although the pocket is not attached by stitching, additional or alternative attachment mechanisms are well within the scope of design choice to the routineer in the implantable electrode art. As to Claims 40-44 and the like, modifying lead length to suit particular patient sizes is notorious in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jayaraman teaches sleeves on a catheter for communicating with a guidewire during implantation. Alliger et al. teach guidewire guide elements on a catheter exterior. Park teaches a pacer lead with a fin (36) for gripping during electrode insertion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Jastrzab whose telephone number is (703) 308-2097. The examiner can normally be reached on Monday through Wednesday and Friday from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes, can be reached on (703) 308-5181. The fax phone number for this Art Unit is (703) 305-3590.


Jeffrey R. Jastrzab
Primary Examiner
Group 3762

October 6, 2003